Food and Drug Administration
Center for Drug Evaluation and Research

Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting
FDA White Oak Campus, Building 31, the Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, MD
September 13, 2012

DRAFT AGENDA

During the morning session, the committee will discuss new drug application (NDA) 203009, lixivaptan, submitted by Cardiokine Biopharma, LLC, for the proposed indication of the treatment of symptomatic hypervolemic and euvolemic hyponatremia associated with heart failure and syndrome of inappropriate antidiuretic hormone (SIADH), respectively.

8:00 a.m.	Call to Order Introduction of Committee	**A. Michael Lincoff, M.D.** Chairperson, CRDAC
	Conflict of Interest Statement	**Kalyani Bhatt, BS, MS** Acting Designated Federal Officer, CRDAC
	Introductory Remarks	**Norman Stockbridge, M.D, Ph.D.** Director, Division of Cardiovascular and Renal Drug Products (DCRP), Office of Drug Evaluation I, (ODEI) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**Sponsor Presentations** Introduction	**Cardiokine Biopharma, LLC** **Alan Roberts** Vice President, Scientific Affairs Cornerstone Therapeutics Inc. Cardiokine Biopharma, LLC
	Hyponatremia and Medical Need Update	**Joseph Verbalis, M.D.** Professor of Medicine Chief, Endocrinology and Metabolism Director, Georgetown-Howard Universities Center for Clinical and Translational Sciences Georgetown University
	Lixivaptan Efficacy - Clinical Program	**Roger Hunter** D & R Biopharma Consulting LLC
	Lixivaptan Efficacy - Clinical Results	**R. William Abraham, M.D.** Professor of Medicine, Physiology and Cell Biology Chair of Excellence in Cardiovascular Medicine Director, Division of Cardiovascular Medicine The Ohio State University

Food and Drug Administration
Center for Drug Evaluation and Research

Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting
FDA White Oak Campus, Building 31, the Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, MD
September 13, 2012

DRAFT AGENDA

Sponsor Presentations (cont.)

Lixivaptan Safety and Tolerability	**James Alexander, M. D.** Senior Director, Clinical Development and Pharmacovigilance, Cornerstone Therapeutics Inc.
Lixivaptan Safety and Tolerability	**R. William Abraham, M.D.**
Benefits of Lixivaptan Therapy	**Arthur Greenberg, M.D.** Professor of Medicine Division of Nephrology Duke University
Moderator	**Roger Hunter**

9:15 a.m. **FDA Presentation**

NDA 203009 Lixivaptan	**Nancy Xu, M.D.** Medical Officer DCRP, OND, CDER, FDA

9:30 a.m. Clarifying Questions from Committee

10:15 a.m. **BREAK**

10:30 a.m. Open Public Hearing

11:00 a.m. Questions to the Committee and Committee Discussion

12:00 p.m. **LUNCH**

Food and Drug Administration
Center for Drug Evaluation and Research

Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting
FDA White Oak Campus, Building 31, the Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, MD
September 13, 2012

DRAFT AGENDA (cont.)

During the afternoon session, the committee will discuss the committee NDA *203826, phenylephrine hydrochloride injection, USP, submitted by West-Ward Pharmaceutical Corp., to increase blood pressure in acute hypotensive states, such as shock and peri-operative hypotension.*

1:00 p.m.	Call to Order Introduction of Committee	**A. Michael Lincoff, M.D.** Chairperson, CRDAC
	Conflict of Interest Statement	**Kalyani Bhatt, B.S., M.S.** Acting Designated Federal Officer, CRDAC
	Introductory Remarks	**Norman Stockbridge, M.D, Ph.D.** Director, Division of Cardiovascular and Renal Drug Products (DCRP), Office of Drug Evaluation I, (ODEI) Office of New Drugs (OND), CDER, FDA
1:15 p.m.	**Sponsor Presentations**	**West-Ward Pharmaceutical Corp.**
	Efficacy	**Joseph Pergolizzi, Jr., M.D.** Anesthesiologist Consultant to West-Ward Adjunct Assistant Professor, John Hopkins University School of Medicine
		Domenic Sica, M.D. Cardiologist Professor of Pharmacology Virginia Commonwealth University Consultant to West-Ward
		John B. Leslie, M.D., M.B.A. Cardiovascular Anesthesiologist Professor of Anesthesiology Mayo Clinic College of Medicine Consultant to West-Ward.
		Raafat S. Hannallah, M.D. Pediatric Anesthesiologist Professor of Anesthesiology and Pediatrics The George Washington University Medical Center Consultant to West-Ward

Food and Drug Administration
Center for Drug Evaluation and Research

Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting
FDA White Oak Campus, Building 31, the Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, MD
September 13, 2012

DRAFT AGENDA (cont.)

	Sponsor Presentations (cont.)	
	Safety	**Jere Vile, M.D., M.P.H.** Safety and Pharmacovigilance Consultant to West-Ward
	Clinical Pharmacology	**Luana Pesco-Koplowitz, M.D., Ph.D.** Clinical Pharmacology/Non-Clinical Dev., Consultant to West-Ward
2:15 p.m.	**FDA Presentation**	
	NDA 203826 Phenylephrine Hydrochloride Injection	**Sudharshan Hariharan, Ph.D.** Clinical Pharmacology Reviewer Division of Clinical Pharmacology I Office of Clinical Pharmacology, CDER, FDA
	Clinical and Efficacy	**Shari Targum, M.D.** Medical Team Leader DCRP, OND, CDER, FDA
2:45 p.m.	Clarifying Questions from Committee	
3:15 p.m.	**BREAK**	
3:30 p.m.	Open Public Hearing	
4:00 p.m.	Questions to the Committee and Committee Discussion	
5:00 p.m.	**ADJOURN**	